REMARKS

I. STATUS OF THE CLAIMS

Claims 1-26 and 28-39 are pending. No new amendments are contained herein. Provided for the Examiner's convenience as Attachment C is a chart of additional microfoam patents and applications that are licensed or assigned to the same assignee.

II. EXAMINER INTERVIEW

Applicants thank Examiner Soroush and Supervisor Richter for granting an in person interview on November 14, 2008. The 35 U.S.C. § 103 rejection was discussed and the Office stated that an additional declaration consistent with Applicants' arguments at the interview would place the application in condition for allowance. The substance of the interview is captured by this response.

III. REJECTION UNDER 35 U.S.C. § 103

The Examiner maintained the rejection of claims 1-26 and 28-36 under 35 U.S.C. § 103 over *Osman et al.* WO 00/72821 (International Application Published Under the PCT, Published 12/07/2000). In addition, the Examiner rejected claims 37-39 under 35 U.S.C. § 103 over *Osman et al.* WO 00/72821 (International Application Published Under the PCT, Published 12/07/2000) in view of *Frullini et al.* (Sclerosing Foam in the Treatment of Varicose Veins and Telengiectases: History and Analysis of Safety and Complications, Published 01/2002).

Specifically, the Examiner asserted that *Osman* teaches "a gas phase comprising carbon dioxide, oxygen, and minor amount of nitrogen gas." Office Action at page 4. The Examiner conceded that *Osman* does not teach the specific amounts of nitrogen gas claimed, 0.0001 to 0.8%, but asserted that the claimed range of nitrogen gas is

obvious because *Osman* "teaches a gas phase comprising preferably 70 to 80% oxygen, 20 to 30% carbon dioxide, and a minor amount of nitrogen," therefore the composition may comprise between 0 to 10% nitrogen "which covers the instantly claimed concentration of 0.01 to 0.6% nitrogen." *Id.* at page 5. In addition, the Examiner asserts that Frullini teaches that "'[t]he definition of a sclerosing foam (SF) is a mixture of gas and liquid sclerosing solution (detergent type) with tension-active properties. The gas must be well tolerated or physiologic and the bubble size less than 100μ.' (See page 11, Column 1, Lines 5-8). Frullini et al. further teaches that there is 'a higher rate of side effects' due to 'the large size of the bubbles which easily spread along vessels.' (See page 12, Column 1, Lines 28-30)." Office Action at pages 6-7. Therefore, the Examiner asserts that "one of ordinary skill in the art at the time of the instant invention would through routine optimization arrive at the instant claimed bubble size diameter in light of the teachings of Frullini et al. One would have been motivated to do so in order to provide foam that has a minimal amount of side effects." *Id.* at page 7. Applicants respectfully traverse.

The Examiner was not persuaded by Applicant's prior arguments because "[i]t is the Examiners position that the prima facia [sic] case of obviousness still holds and applicants have not provided a proper side by side comparison of a foam comprising liquid sclerosing agent and a gas phase comprising 0.0001% to 0.8% nitrogen by volume and at least one other physiologically acceptable gas to a foam comprising liquid sclelerosing [sic] agent and a gas phase comprising a physiologically acceptable gas and nitrogen gas concentrations outside the instantly claimed range taught by Osman et al. in order to show unexpected results." Office Action at page 5.

Applicants respectfully disagree. However, to further prosecution and as agreed at the interview, Applicants herein submit a declaration from inventor David Wright describing a study published as *Eckmann et. al.,* Microvascular Embolization Following Polidocanol Microfoam Sclerosant Administration, *Dermatol. Surg.* 31: 636-43 (2005). The *Eckmann et al.* study reports a side-by-side comparison in rats of (1) an air based foam, (b) a foam with 7% nitrogen, and (c) a foam with 0.01-0.8% nitrogen demonstrating that a foam with a nitrogen gas concentration within the claimed range shows unexpected results. *See Wright* declaration, attachment A and images from *Eckmann et al.,* attachment B.

Eckmann et al. injected each foam into the femoral artery of the rat and measured the number and size of the gas bubbles in the cremaster arterial microcirculation. *Wright* declaration, attachment A at ¶7. In addition, the authors observed gas bubble behavior (e.g., whether the bubbles blocked the arteries and if they did, how fast they cleared). *Id.*

As explained by Dr. Wright, the *Eckmann et al.* study surprisingly demonstrated that the 0.01-0.8% nitrogen foam displayed distinct differences from the 7% nitrogen foam. *Id.* at ¶12. Moreover, these differences render the 0.01-0.8% nitrogen foam safer than the 7% nitrogen foam. *Id.* at ¶13.

Therefore, Applicants have, as requested by the Examiner, submitted a side-by-side comparison of foam with a nitrogen content within the claimed range (0.01-0.8% nitrogen) with a foam taught by *Osman*, demonstrating the unexpected results of the instant foam. Therefore, Applicants have rebutted any *prima facie* case of obviousness.

For at least the above reasons, Applicants respectfully request withdrawal of the rejection as to claims 1-26 and 28-39 under 35 USC § 103.

IV. CONCLUSION

In view of the foregoing remarks and attached declaration, Applicants respectfully request reconsideration of claims 1-26 and 28-39 and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: December 8, 2008

By: _____
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Attachments:

A: *Wright, D.,* declaration, November 24, 2008.

B: *Eckmann et al.,* Figure 4 images.

C: Chart of microfoam patents and applications.